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10/598,315	04/08/2008	Lawrence Solomon	SLP-035	2612

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,315	SOLOMON ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 7-33* is/are pending in the application.

4a) Of the above claim(s) *27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 7-26 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 07/17/09 and 10/05/09 are acknowledged.

2. Claims 4-6 were cancelled. Claims 27-32 were withdrawn. Claims 1, and 7-8 were amended (07/17/09).

3. Claims 1-3, 7-26 and 33 are included in the prosecution.

Response to Arguments

Claim Objections

4. In light of Applicant's cancellation of claim 4, the objection with respect to this claim is rendered moot.

Rejection of claims 1-3, 5, 12-15, and 21-26 under 35 USC § 102(b)

5. In light of Applicant's amendment of claim 1 to include the limitations of claim 4, Applicant's arguments, see Page 8, filed 07/17/09, with respect to the rejection of claims 1-3, 5, 12-15, and 21-26 under 35 USC § 102(b) as being anticipated by Shah et al. (US 4,824,677) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration a new ground of rejection (necessitated by Applicant's amendment) is made under USC § 103(a) over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1).

Rejection of claims under 35 USC § 103(a)

6. In light of Applicant's cancellation of claims 4 and 6, the rejection with respect to these claims is rendered moot.

7. Applicant's arguments, see Page 8, filed 07/17/09, with respect to the rejection of claims 7-11, 16-17 and 33 under 35 USC § 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1) have been fully considered but are not persuasive.

Applicant argues that the Shah patent does not disclose the concept of providing a segment in a divisible table where the first segment has either an undetectable amount of a drug, a pharmacologically ineffective amount of a drug or a pharmacologically effective amount of a drug or drugs that are present in the second segment. Applicant argues that: "The Conte patent requires that the first and second contiguous segments must both contain drugs and that the third non-contiguous segment be the segment that has no drug. If one were to make the tablet defined by the amended claims of the present application, the teachings of Conte would have to be disregarded as Conte explicitly requires that the only tablet that he discloses must have two contiguous active layers. It is not obvious to make a tablet that has a structure which can only be made by ignoring the teachings of the prior art. Even when Conte is combined with Shah, there is no reason to modify Conte and have only one active segment contiguous with an inactive segment."

This is not persuasive because while Shah does not expressly teach a first segment that contains either an undetectable amount of a drug, a pharmacologically ineffective amount of drug, or a pharmacologically effective quantity of said drug or drugs present in said second segment, but has fewer milligrams of said drug or drugs relative to the excipients in each segment than does said second segment, this deficiency is remedied by Conte. Conte teaches the following (Abstract).

> Pharmaceutical tablet consisting of a first layer containing one or more drugs with immediate or controlled release formulation, a second layer containing one or more drugs, either equal to or different from the first layer, with slow release formulation, and a low-permeability barrier-type layer coating said second layer or, alternatively, placed between the first and second layer and, if necessary, containing a drug.

Therefore, a person having ordinary skill in the art would know that it is possible to prepare a layered tablet containing: (a) two contiguous active containing layers and a barrier layer **or** (b) a barrier layer between the first and second active containing layers. The barrier layer of Conte may not contain any active drugs (Conte says "if necessary, containing a drug.")

Based on the teaching of Conte a person having ordinary skill in the art would find it obvious to have alternating contiguous active segments and inactive segments. The inclusion or exclusion or active drugs from particular segments would have been obvious over the layered tablet taught by Conte.

One of ordinary skill in the art would find it obvious to combine the teachings of Shah and Conte because both references teach the slow or sustained release characteristics of drugs. One of ordinary skill in the art would find it obvious to include the barrier layer in the divisible tablet formulation of Shah in order to optimize the sustained release profile of the chosen active drug.

Therefore, the rejection of 02/17/09 is maintained.

8. In light of Applicant's amendment of claim 1 to include the limitations of claim 4, Applicant's arguments, see Page 10, filed 07/17/09, with respect to the rejection of claims 17-18 under 35 USC § 103(a) as being unpatentable over Shah et al. (US

4,824,677) in view of Addicks et al. (US 5,041,430) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration a new ground of rejection (necessitated by Applicant's amendment) is made under USC § 103(a) over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1) and further in view of Addicks et al. (US 5,041,430).

9. In light of Applicant's amendment of claim 1 to include the limitations of claim 4, Applicant's arguments, see Page 10, filed 07/17/09, with respect to the rejection of claims 17 and 19 under 35 USC § 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Eberlin et al. (US 3,696,091) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration a new ground of rejection (necessitated by Applicant's amendment) is made under USC § 103(a) over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1) and further in view of Eberlin et al. (US 3,696,091).

10. In light of Applicant's amendment of claim 1 to include the limitations of claim 4, Applicant's arguments, see Page 11, filed 07/17/09, with respect to the rejection of claims 17 and 20 under 35 USC § 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Franz et al. (US 6,555,581 B1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration a new ground of rejection (necessitated by Applicant's amendment) is made under USC § 103(a) over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1) and further in view of Franz et al. (US 6,555,581 B1).

Provisional Rejection of claims under obviousness-type double patenting

11. In light of Applicant's cancellation of claims 4 and 6, the rejection with respect to these claims is rendered moot.

12. Applicant's arguments, see Page 11, filed 07/17/09, and Page 8, filed 10/05/09 with respect to the rejection of claims 1-3, 7-26 and 33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of Application No. 11/441,455 have been fully considered but are not persuasive.

Applicant argues that "since the present double patenting rejection is a provisional rejection between two applications, it is believed that the applicant may wait until one application is granted as a patent before deciding to amend, abandon or disclaim. It is not believed that such action is required to be taken in response to a provisional double patenting rejection."

Until such time that a terminal disclaimer is filed the provisional rejection of 02/17/09 will be maintained.

13. Applicant's arguments, see Page 11, filed 07/17/09, with respect to the rejection of claims 1-3, 7-26 and 33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 7,329,418 have been fully considered but are not persuasive.

Applicant argues that "the claims of the '418 patent require a three layer structure and a particular height to width ratio. These structural elements do not make the claimed tablet obvious. This is particularly evident for claim 18, 19 and 20 which points out particular drugs that are not pointed out by the claims of the '418 patent."

This is not persuasive because one of ordinary skill in the art would find it obvious to manipulate the structural elements of a layered tablet during the process of

routine experimentation and the difference of immediate release as required by the claims of the '418 patent would have been an obvious variation.

Therefore, the rejection of 02/17/09 is maintained.

14. Applicant's arguments, see Page 11, filed 07/17/09, with respect to the rejection of claims 1-3, 7-26 and 33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 7,318,935 have been fully considered but are not persuasive.

Applicant argues that "the claims of the '935 patent also require a three layer structure and a particular height to width ratio. In addition, the subject matter of claims 18-20 of the present application are not made obvious by the claims of the '935 patent."

This is not persuasive because one of ordinary skill in the art would find it obvious to manipulate the structural elements of a layered tablet during the process of routine experimentation and the difference of particular active ingredients as required by instant claims 18-20 would have been obvious variations.

Therefore, the rejection of 02/17/09 is maintained.

NEW REJECTIONS NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1-3, 7-17, 21-26, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1).

The claimed invention is a pharmaceutical tablet comprising a first unitary segment one face of which is contiguous with a second unitary segment that contains a drug or drugs, where the first segment contains either an undetectable amount of a drug, a pharmacologically ineffective amount of drug, or a pharmacologically effective quantity of the drug or drugs present in the second segment, but has fewer milligrams of the drug or drugs relative to the excipients in each segment than does the second segment.

Shah teaches divisible tablets for facilitating fractional dosing of medication (Col. 1, lines 6-9). The divisible tablets "will retain their sustained release property when divided into two or more discrete segments … the sustained release characteristics of the whole tablet are retained by each segment of the tablet" (Col. 2, lines 11-20). Figures 1-7 illustrate bi-dosage divisible tablets and Figures 8 and 9 illustrate tri-dosage tablets (also Col. 3, line 6 to Col. 4, line 47). Figures 10 and 11 illustrate an elliptical bi-dosage tablet (also Col. 4, lines 48-58).

Shah does not expressly teach a first segment that contains either an undetectable amount of a drug, a pharmacologically ineffective amount of drug, or a pharmacologically effective quantity of said drug or drugs present in said second segment, but has fewer milligrams of said drug or drugs relative to the excipients in each segment than does said second segment.

Conte teaches a multi-layer tablet where the first layer contains one or more drugs with immediate or controlled release formulation, the second layer contains one or more drugs with slow release formulation, and a third layer, which is a low-permeability barrier coating (Col. 3, lines 33-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah, combine it with the tablet that consists of two layers of drugs and one barrier (non-drug) layer that can be placed as a contiguous layer or as a layer between two active containing segments, as taught by Conte, and produce the instant invention.

One of ordinary skill in the art would combine the tablets of Shah and Conte because both references teach the slow or sustained release characteristics of drugs. One of ordinary skill in the art would find it obvious to include the barrier layer in the divisible tablet formulation of Shah in order to optimize the sustained release profile of the chosen active drug.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 1-2 and 7-9, the pharmaceutical tablet comprising a first segment one face of which is contiguous with a plurality of compositionally substantially

identical unitary segments that contain a drug or drugs would have been obvious over the tablets that can be divided into two or more discrete segments and where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah (Col. 2, lines 11-20). Since each segment retains the release characteristics of the whole tablet, the tablet taught by Shah has compositionally identical segments that contain a drug or drugs. Regarding instant claim 2, the limitation of the first unitary segment and the second unitary segment being derived from the same divided layer or layers would have been obvious over the area 24, which is adjacent to the common edge structure 23, as illustrated in Figure 1 by Shah.

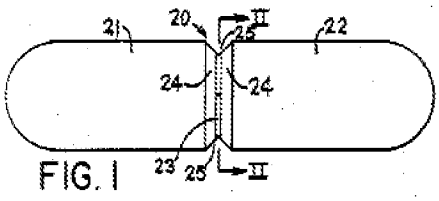

FIG. 1

Regarding the limitation of a first segment that contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug would have been obvious over the barrier layer without any drug, as taught by Conte (Col. 3, lines 33-44 and Col. 6, lines 23-35). A person having ordinary skill in the art would know that it is possible to prepare a layered tablet containing: (a) two contiguous active containing layers and a barrier layer **or** (b) a barrier layer between the first and second active containing layers. The barrier layer of Conte may not contain any active drugs (Conte says “if necessary, containing a drug.”)

Based on the teaching of Conte a person having ordinary skill in the art would find it obvious to have alternating contiguous active segments and inactive segments. The inclusion or exclusion or active drugs from particular segments would have been obvious over the layered tablet taught by Conte.

Regarding instant claim 3, the one or more additional unitary segments in addition to the first and second unitary segments that are optionally present and are derived from the same layer or layers as said first unitary segment would have been obvious over the two or more discrete segments of the divisible tablet, as taught by Shah (Col. 2, lines 11-20).

Regarding instant claim 10, the limitation of the first segment that is derived from a granulation that does not contain a drug would have been obvious over the granulation that does not contain a drug for the barrier layer, as taught by Conte (Col. 6, lines 23-35).

Regarding instant claim 11, the limitation of additional unitary segments that are contained in the tablet which are compositionally different from the composition of said first unitary segment and said second unitary segment and are derived from a granulation containing a drug would have been obvious over the compositionally different granulations for layers 4 and 5, as taught by Conte (Col. 6, lines 1-13 and lines 47-61). Layer 4 requires lactose, starch, carboxymethyl starch and cross-linked polyvinylpyrrolidone, which are not required for layer 5. The granulations for layers 4 and 5 contain a drug (ephedrine hydrochloride).

Regarding instant claim 12, the limitation of the first unitary and the second unitary segments that are outer segments would have been obvious over the divisible tablets illustrated by Figures 1, 6, 8, and 10 by Shah. The divisible segments are on the outside of the tablet.

Regarding instant claim 13, the limitation of the first unitary segment and the second unitary segment adjoining other unitary segments that are outer segments would have been obvious over Figure 8, as disclosed by Shah. Figure 8 illustrates three unitary segments (61, 62 and 63) and all of these are outer segments.

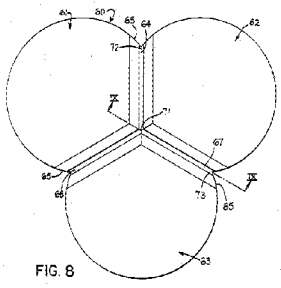

FIG. 8

Regarding instant claim 14, the limitation of interposed unitary segments between the first unitary segment and the first segment would have been obvious over Figure 1 as illustrated by Shah. Unitary segments 24 are interposed between segments 21 and 22.

Regarding instant claim 15, the limitation of a substantially vertical score in said first segment, said score being vertically aligned with the center of the space between said first unitary segment and said second unitary segment would have been obvious over the divisible tablet with the notch (25) located between the unitary segments (24), as illustrated in Figure 1 by Shah.

Regarding instant claim 16, the limitation of two additional unitary segments which are compositionally identical would have been obvious over the two or more discrete segments of the divisible tablet taught by Shah (Col. 2, lines 11-20). One of ordinary skill in the art would find it obvious to include additional segments based on the desired fractions or doses of the whole tablet.

Regarding instant claims 17 and 33, the limitation of the drugs would have been obvious over the non-steroid anti-inflammatory drugs (used for the treatment of pain) and drugs for the prevention of anginal and hypertensive attacks taught by Conte (Col. 5, lines 6-25).

Regarding instant claims 21-22, the limitation of the first segment adjoining a plurality of unitary segments on the side of said first segment that is opposite the surface adjoining said first and second unitary segments would have been obvious over the divisible tablet, as illustrated in Figure 8 by Shah. Segment 61 adjoins unitary segments 65.

Regarding instant claims 23-26, the methods of breaking a pharmaceutical tablet would have been obvious over the tablet that may be divided into discrete segments and administered, as taught by Shah (Col. 2, lines 11-20).

17. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1) and further in view of Addicks et al. (US 5,041,430).

The teachings of Shah and Conte are stated above.

Shah and Conte do not expressly teach warfarin as the drug in the tablet.

Addicks teaches a multilayer tablet that comprises warfarin (Col. 7, line 46 to Col. 8, line 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah, combine it with the tablet that consists of two layers of drugs and one barrier (non-drug) layer that can be placed as a contiguous layer or as a layer between two active containing segments, as taught by Conte, combine it with the tablet that comprises warfarin, as taught by Addicks, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the divisible tablet as taught by Shah.

Regarding instant claims 17-18, the limitation of warfarin would have been obvious over the warfarin in the multilayer tablet taught by Addicks (Col. 7, line 46 to Col. 8, line 9).

18. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1) and further in view of Eberlin et al. (US 3,696,091).

The teachings of Shah and Conte are stated above.

Shah and Conte do not expressly teach digoxin as the drug in the tablet.

Eberlin teaches a tablet that comprises digoxin (Col. 12, lines 20-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah, combine it with the tablet that consists of two layers of drugs and one barrier (non-drug) layer that can be placed as a contiguous layer or as a layer between two active containing segments, as taught by Conte, combine it with the tablet that comprises digoxin, as taught by Eberlin, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the divisible tablet as taught by Shah.

Regarding instant claims 17 and 19, the limitation of digoxin would have been obvious over the digoxin in the tablet taught by Eberlin (Col. 12, lines 20-45).

19. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1) and further in view of Franz et al. (US 6,555,581 B1).

The teachings of Shah and Conte are stated above.

Shah and Conte do not expressly teach levothroxine as the drug in the tablet.

Franz teaches a tablet that comprises levothyroxine sodium (Col. 17, Table 1, lines 10-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah, combine it with the tablet that consists of two layers of drugs and one barrier (non-drug) layer that can be placed as a contiguous layer or as a layer between two active containing segments, as taught by Conte, combine it with the tablet that comprises levothyroxine, as taught by Franz, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the divisible tablet as taught by Shah.

Regarding instant claims 17 and 20, the limitation of levothroxine would have been obvious over the levothyroxine in the tablet taught by Franz (Col. 17, Table 1, lines 10-22).

MAINTAINED REJECTIONS

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-3, 7-26 and 33 **remain** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14 and 17 of copending Application No. 11/441,455 (the '455 Application).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The difference between instant claims and those of the '455 Application is that instant claims require unitary segments. However, one of ordinary skill in the art would find it obvious to design the tablet with unitary segments in order to accomplish partial dosing of the active.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-3, 7-26 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-15 and 20 of U.S. Patent No. 7,329,418 (the '418 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference of immediate release as required by the claims of the '418 patent would have been an obvious variation to one of ordinary skill in the art.

23. Claims 1-3, 7-26 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 6-11 of U.S. Patent No.

7,318,935 (the '935 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference of tablet height greater than tablet width as required by the claims of the '935 patent would have been an obvious variation to one of ordinary skill in the art.

Conclusion

24. No claims are allowed.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615